

## 6.0 TRANSPLANTATION OF NON-RESIDENT ALIENS

The following policies apply for organ transplantation of non-resident aliens and for importation or exportation of organs for transplantation.

### 6.1 DEFINITIONS. The following definitions apply to these policies:

**6.1.1 Non-Resident Alien.** A non-resident alien is an individual granted permission by the United States Government to enter the United States on a temporary basis as a non-immigrant alien for purposes which include tourism, business, education, medical care, or temporary employment.

**6.1.2 Domestic, American Candidate or Resident Alien.** A domestic, American candidate or resident alien is an individual who is either an American citizen or is an immigrant alien granted permanent resident status by the United States Government or any individual, regardless of immigrant status, qualified for health care entitlement funds from state or federal government sources.

### 6.2 GUIDELINES. Any member transplant center which agrees to list non-resident aliens on its Waiting List shall adhere to the following guidelines:

**6.2.1 Nondiscrimination/Organ Allocation.** Selection, from the Waiting List, of non-resident alien candidates for transplantation shall be based on the same allocation policies (Section 3.0) mandated by the Board of Directors for selection of domestic candidates. Such selection shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion or financial status.

**6.2.2 Transplant Centers.** Transplantation of each non-resident alien should be done in a transplant center with a historical pattern of international referral and a reputation for both treatment of primary and endstage organ disease and transplantation, with regard to the particular organ(s) being transplanted.

**6.2.3 Fees.** Transplantation of non-resident aliens is a humanitarian act and shall not be done for financial advantage. Transplant centers listing non-resident aliens on their Waiting Lists shall charge non-residents the same fees for service as those charged to domestic candidates and recipients.

**6.2.4 Referrals.** Members shall not enter into formal contractual arrangements with foreign agencies or governments for the transplantation of non-resident aliens. OPTN members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case- by-case and physician-to-physician basis.

**6.2.5 Community Participation.** Each member center which lists non-resident aliens on its Waiting List should establish a mechanism for community participation and review of its candidate acceptance criteria.

**6.2.6 Training Programs.** To enhance transplantation in underserved nations, it is desirable for transplant centers engaged in the transplantation of non-resident aliens to establish training programs which include transplantation training of physicians from underserved nations and educational programs designed for development of transplantation services in those

underserved nations.

- 6.3 AUDIT.** As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and audit, at its discretion, all center activities pertaining to transplantation of non-resident aliens. The Committee will review the activities of each member transplant center where non-resident alien recipients constitute more than 5% of recipients of any particular type of deceased organ. At centers where non-resident alien transplant recipients constitute more than 5% of recipients of any particular organ type, circumstances underlying the transplants for non-resident aliens will be reviewed by the Committee. Special consideration will be given to programs served by OPOs with non-resident alien organ donors.

- 6.4 EXPORTATION AND IMPORTATION OF ORGANS-DEVELOPMENTAL STATUS.** International exchange of organs for transplantation is technically feasible but remains an uncommon procedure. The OPTN regards international sharing of organs to be in an early phase of development.

- 6.4.1 Exportation.** Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

- 6.4.2 Developmental Protocols in International Organ Exchange.** After prior approval by the OPTN, members may enter into formal organ exchange arrangements, each not to exceed two years in duration, with a foreign transplant program or programs. Negotiations with foreign transplant programs or foreign agencies which include importing organs must be approved by the Ad Hoc International Relations Committee. Importation of organs is defined in Policy 6.4.5 (Importation). Proposed protocols must be submitted to the OPTN describing the basis for such arrangements, expected benefits to both foreign and domestic participants, credentials of the foreign source, number and type of organs anticipated to be involved, and plans for allocation procedures and reporting of results. Proposed protocols must include a requirement for the donor organization to submit documentation certifying the informed consent of the donor or his or her legal representative. Proposed protocols must also include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized U.S. standards for domestic organ procurement. Proposed protocols must include a requirement for the donor organization to submit documentation of the donor's ABO. Proposed protocols will be reviewed by the Ad Hoc International Relations Committee, which will then make recommendations to the Board of Directors.

- 6.4.2.1** All foreign organ exchanges must be reported within 72 hours to the Organ Center. All exchanges must satisfy policy that no organs can be exported from the United States without first a determination having been made by the Organ Center that there is no suitable recipient for that organ on the Waiting List. All imported organs will be allocated first within the local area of the OPO that arranged the importation of the organ and in accordance with the allocation policy for that organ. If no recipient is found within the local area of the OPO that arranged the importation of the organ, then the organ shall be allocated outside the local area in a manner consistent with the policies which apply to that organ.

OPO's are required to execute the Match System (UNet<sup>sm</sup>) for the allocation of all organs. The importing OPO must provide the minimum required information about the foreign donor consistent with Policy 3.5.9 (Minimum Information/

Tissue for Kidney Offer), Policy 3.6.9 (Minimum Information for Liver Offers), Policy 3.7.12 (Minimum Information for Thoracic Organ Offers, and Policy 3.8.5 (Minimum Information for Pancreas Offers) and comply with the ABO verification requirements in accordance with Policy 3.2.3 (Match System Access).

**6.4.2.2** All approved international organ exchange protocols will be reviewed at least annually by the Ad Hoc International Relations Committee. Any additional policies regarding international exchange agreements will be developed by the Committee based on experience acquired pursuant to approved developmental protocols. It is a goal of the OPTN that international exchange of organs between OPTN members and foreign programs will foster the development of international organ sharing. It is hoped that such exchanges will occur through the regular national OPTN system, after feasibility has been established.

**6.4.2.3** Importation of an organ for human transplantation in the United States is appropriate only if the foreign source is an OPTN-recognized source, i.e., organ transplant center or organ procurement program specifically authorized as a transplant center or organ procurement program by an appropriate agency of its national government. The OPO or transplant center responsible for importation of an organ must obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

**6.4.3** **Ad Hoc Organ Exchange.** Except as provided for in approved international exchange protocols, all offers of organs for human transplantation from foreign sources must be made to the Organ Center. If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer. No more than six exchanges by any member with any foreign program(s) will be allowed on an ad hoc basis. Additional exchanges must be made as part of an international organ exchange protocol approved by the Ad Hoc International Relations Committee and Board of Directors.

Imports of organs from foreign sources on an ad hoc basis must meet the requirements for importing organs and allocation of those organs under organ exchange protocols found in Policy 6.4.2.1. Additionally, organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after cardiac death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement. Organs imported by OPOs must include documentation from the donor organization certifying the informed consent of the donor or his or her legal representative. Organs imported by OPOs must include documentation from the donor organization verifying the donor's ABO.

**6.4.3.1** **Ad Hoc Organ Exchange Review.** Ad hoc organ exchange will be reviewed annually by the Ad Hoc International Relations Committee.

**6.4.4** **Ethical Practices.** No member will engage in practices which might discredit the transplant community. Organs accepted for importation must be from deceased donors and must have been voluntarily donated. Organs imported from living donors or organs for which compensation has been made or promised are not acceptable for exchange or acceptance by members.

**6.4.5** **Importation.** An imported organ is defined as an organ that is procured outside of the

United States of America or its territories. Imported organs must meet the requirements of Policy 6.4.2 (Developmental Protocols in International Organ Exchange) and/or Policy 6.4.3 (Ad Hoc Organ Exchange).

- 6.5 VIOLATIONS OF POLICIES.** Violations of import/export policies (6.2.2 through 6.2.4 and 6.4.1 through 6.4.4) will be reported to the Membership and Professional Standards Committee and may result in suspension of membership by the Board of Directors. Persistent violations of Policy 6.3 (Audit) without justification or explanation, or failure to respond to inquiries will be reported to the Membership and Professional Standards Committee.